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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,085	10/24/2001	Avi J. Ashkenazi	GNE.2630PIC73	4364
35489	7590	01/11/2005	EXAMINER	
HELLER EHRMAN WHITE & MCAULIFFE LLP			SPECTOR, LORRAINE	
275 MIDDLEFIELD ROAD			ART UNIT	
MENLO PARK, CO 94025-3506			PAPER NUMBER	
			1647	
DATE MAILED: 01/11/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,085

Applicant(s)

ASHKENAZI ET AL.

Examiner

Lorraine Spector, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2004 and 25 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-65,68-70 and 74-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-65,68-70 and 74-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 58-65, 68-70 and 74-84 are pending and under consideration.

The previous rejections under 35 U.S.C. §112, second paragraph are withdrawn in view of applicants amendments. New rejections apply.

The objection to the specification is overcome by applicants amendment.

The rejection of claims 58-63 and 70-77 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of applicants amendments.

Formal Matters

The new title of the invention is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58-65, 68-70 and 74-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 has been amended such that the preamble recites "An isolated nucleic acid encoding a polypeptide", however, part (c) of the claim requires the polypeptide to have identity to a nucleic acid sequence. As polypeptides do not have identity to nucleic acids, the claim is indefinite. Claims 59-63 are similarly indefinite.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58-65, and 74-77 remain, and newly submitted claims 78-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid of SEQ ID NO: 205 or fragments of such that are usable as hybridization probes, does not reasonably provide enablement for nucleic acids 80, 85, 90, 95 or 99% identical to such, nor which encode a protein 80, 85, 90, 95 or 99% identical to the protein of SEQ ID NO: 205, nor nucleic acids which hybridize to any of the above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. This rejection is maintained for reasons of record in the previous Office Action, mailed 2/6/2004.

Applicants argument filed 7/20/2004 has been fully considered but is not deemed persuasive. Applicants argue that the amendment of claim 58 to recite that "said nucleic acid is amplified in lung cancer" fulfils the requirement of 35 U.S.C. §112, first paragraph, as "one skilled in the art would know exactly how to make and use these nucleic acids for the diagnosis of lung and colon cancer; for example, by using diagnostic methods based on hybridization to such amplified sequences." This argument has been fully considered but is not deemed persuasive because one cannot make what one has no conception of. The specification provides a single nucleic acid, SEQ ID NO: 205, which was found to be amplified in lung squamous cell carcinoma and colon adenocarcinoma. No other such sequences have been disclosed. It is not predictable that all, or even a significant proportion of the claimed sequences, which encompass all possible degenerate variants of SEQ ID NO: 205, would similarly be found to be amplified in said cancers. What applicants argue is merely an invitation to experiment to determine whether

other sequences related to SEQ ID NO: 205 by virtue of encoding the same protein would be similarly amplified. Such an invitation to experiment is not enabling of the scope of the claims, as it would require undue experimentation to determine operative species within the metes and bounds of the claims.

With further respect to newly introduced claims 78-84, it is noted that the claims do not require that the claimed nucleic acid be amplified in lung or colon tumors, accordingly the rejection applies as made in the previous Office Action. The newly introduced claims seek coverage of any nucleic acid that could be obtained under specified conditions using the disclosed nucleic acids; the specification as filed does not teach how to use the breadth of such nucleic acids, for reasons of record. It remains that there is but a single nucleic acid disclosed with reference to PRO853, SEQ ID NO: 205. In the absence of sufficient guidance, it would require undue experimentation to enable a commensurate number of the sequences that are encompassed by the Claims.

Claims 58-65, and 74-77 remain, and newly submitted claims 78-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record in the previous Office Action, mailed 2/6/2004.

Applicants traversal that the recitation of a utility in the claims overcomes the rejection. This argument has been fully considered but is not deemed persuasive because applicants have not established that there is any conception of nucleic acids in a manner commensurate in scope with the claims. All applicants have presented is a single nucleic acid found to be amplified in cancers, and the germ of an idea that there might be variants of the nucleic acid that would be similarly associated. There is no evidence of the actual conception of such nucleic acids, nor is there any evidence of record that they exist. . Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and

Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. Accordingly, the rejection is maintained.

Rejections Over Prior Art:

Priority is set at 12/22/98.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 78-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsubara et al., locus AAT19666, published in WO 95/14772.

Matsubara discloses a sequence that has 100% identity to nucleotides 1744-1835 of SEQ ID NO: 205, a length of 92 nucleotides' identity. The sequence of Matsubara et al. would hybridize under stringent conditions to SEQ ID NO: 205 given this identity.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to 571-273-8300. Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lorraine Spector, Ph.D.
Primary Examiner

1/10/2005